PATENT
Attorney Docket No. MDS-009CN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT(S):	Modell *et al.*	CONFIRMATION NO.:	6590
SERIAL NO.:	09/841,325	GROUP NO.:	3737
FILING DATE:	April 24, 2001	EXAMINER:	Smith, Ruth S
TITLE:	Method and Apparatus for Scanning a Biological Sample		

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APPEAL BRIEF

This Appeal Brief is submitted in accordance with 37 C.F.R. § 41.37 and in furtherance of the Notice of Appeal filed November 22, 2006, in support of the appeal from the final rejection of claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 in the above-identified application. A Notice of Panel Decision from Pre-Appeal Review of the rejected claims, mailed on March 2, 2007, precipitated this Appeal Brief.

Appellants authorize a charge to deposit account number 07-1700 to cover the fee for filing of this Appeal Brief and petition for one month extension of time. Appellants believe that no additional fee is due. However, please consider this a conditional petition for the proper extension, if one is required, and a conditional authorization to charge any related extension fees or other fees necessary for entry and consideration of this Brief to Appellants' undersigned counsel's deposit account number 07-1700 with reference to docket number MDS-009CN.

REAL PARTY IN INTEREST

This application is assigned to MediSpectra, Inc. The assignment was recorded at Reel 013604, Frame 0419, on December 26, 2002. Accordingly, the real party in interest is MediSpectra, Inc.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences pending in the above-identified application that will directly affect or will be directly affected by the Board's decision in the present appeal.

STATUS OF CLAIMS

The application as filed contained 104 claims. Claims 1-104 were canceled, and new claims 105-124 added, by a Preliminary Amendment of April 24, 2001. Claim 112 was canceled, and new claims 125-147 added, by an Amendment and Response of December 1, 2003. Claims 114 and 127-147 were canceled, and new claims 148-149 added, by an Amendment and Response of May 26, 2004. Claim 149 was canceled by an Amendment and Response of December 23, 2004. Claim 120, 151, 157, 158, 161, and 161 were canceled by an Amendment and Response of June 17, 2005. New claims 170 and 171 were added by an Amendment and Response of March 20, 2006. Claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 are currently pending. All of the pending claims (i.e., claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171) have been rejected and are the subject of this appeal.

STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Office action mailed on August 24, 2006.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 105 relates to a method of sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample.[1] The method includes the steps of sequentially illuminating a plurality of substantially non-overlapping regions of a sample with electromagnetic radiation using illuminating optics, and collecting electromagnetic radiation emanating from said regions of said sample using collecting optics.[2] A disposable device for use with a single patient is positioned to protect said patient during said scanning.[3] The method is performed without the sample being surgically exposed.[4] Dependent claims 106-111, 113, 115-119, 121-126, 148, 150, and 170 depend, either directly or indirectly, from independent claim 105, and contain further limitations to independent claim 105.

Independent claim 152 relates to an apparatus for sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample.[5] The apparatus includes illuminating optics for sequentially illuminating said plurality of substantially non-overlapping regions of said sample with electromagnetic radiation.[6] The apparatus also includes collecting optics for collecting electromagnetic radiation emanating from said regions of said sample,[7] and a disposable device for use with a single patient, said disposable device configured to protect

[1] Specification, page 1, line 11; page 12, line 21 to page 13, line 6.
[2] Id.
[3] Specification, page 37, line 28 to page 40, line 25.
[4] Specification, page 10, line 29 to page 11, line 5; page 38, lines 12-22; Figure 17.
[5] Specification, page 1, line 11; page 12, line 21 to page 13, line 6.

said patient during said scanning.[8] The apparatus does not require the sample to be surgically exposed.[9] Dependent claims 153-156, 159, 160, 162-168, and 171 depend, either directly or indirectly, from independent claim 152, and contain further limitations to independent claim 152.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 105-107, 109, 110, 115, 125, 126, 152-156, 159-160, 165-167, 170, and 171 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,424,852 to Zavislan (hereinafter "Zavislan") in view of U.S. Patent No. 4,362,166 to Furler (hereinafter "Furler"), U.S. Patent No. 5,337,734 to Saab (hereinafter "Saab"), or U.S. Patent No. 6,115,523 to Choi (hereinafter "Choi"). Claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 are rejected under 35 U.S.C. §103(a) as being unpatentable over Zavislan in view of Furler, Saab, or Choi, and further in view of U.S. Patent No. 5,693,043 to Kittrell (hereinafter "Kittrell"). Claims 116, 117, 122, 124, 163, and 164 are rejected under 35 U.S.C. §103(a) as being unpatentable over Zavislan in view of Furler, Saab, or Choi, and further in view of Kittrell and U.S. Patent No. 6,210,331 to Raz (hereinafter "Raz").

ARGUMENT

Claims 105-107, 109, 110, 115, 125, 126, 152-156, 159-160, 165-167, 170, and 171 constitute nonobvious subject matter and are patentable under 35 U.S.C. §103(a) over Zavislan in view of Furler, Saab or Choi.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the

[6] Id.
[7] Id.
[8] Specification, page 37, line 28 to page 40, line 25.

knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Appellants disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP § 706.02(j).

In the present case, the Examiner has failed to find references that teach the limitations of claims 105-107, 109, 110, 115, 125, 126, 152-156, 159-160, 165-167, 170, and 171. The Examiner, in other words, has not met the basic requirements of 35 U.S.C. §103(a). Specifically, a claim element that is clearly not present in applied art is not included in the Examiner's analysis.

Each of the pending independent claims 105 and 152 recites the limitation, "an internal biological sample, ... said sample not surgically exposed". The Examiner fails to show where this limitation allegedly appears in the cited art.

In the 8/24/06 Office Action, the Examiner alleges that Zavislan teaches, "The tissue can be internal biological tissue as disclosed in column 7, lines 34-47." However, the Examiner does not allege anywhere in the Office Action that Zavislan teaches or suggests an internal biological tissue not surgically exposed. Furthermore, all of the rejections cite a combination of references, all including Zavislan.

Zavislan describes a device for examination of the skin. Zavislan does not teach or suggest "an internal biological sample, ... said sample not surgically exposed". Even if one

[9] Specification, page 10, line 29 to page 11, line 5; page 38, lines 12-22; Figure 17.

could argue the few lines of Zavislan dealing with "internal tissues" (col. 7, lines 45-47) enables one to use its skin examination device to examine a surgically-exposed cervix (such surgical exposure being necessary, as admitted at lines 45-47 of Zavislan, given the device described therein), this would still not teach or suggest scanning "regions of an internal biological sample ... said sample not surgically exposed," [emphasis added] as recited in each of independent claims 105 and 152.

Methods and systems according to the invention can be used to scan internal tissue that is accessed via a probe – for example, using equipment such as an endoscope, laparoscope, or arthroscope – without the need for surgically exposing the tissue. For example, the specification states at page 11, lines 1-5:

> To provide internal analysis, the invention is adapted to work with existing endoscopes, laparoscopes, or arthroscopes. To adapt the invention for diagnostic purposes involving contact with biological tissues, the invention can be provided with a covering that can be disposable to insulate the instrument from contact with biological tissues.

Furthermore, Figure 17 shows an embodiment of the invention positioned within a body cavity (within the female perineum) for scanning of non-surgically exposed regions of cervical tissue.

In contrast, Zavislan briefly refers to scanning of surgically exposed cervical tissue, wherein the cervical tissue is maintained under tension or compression during scanning. For example, Zavislan states, at column 7, lines 41-48:

> Each of the above confocal imaging system embodiments provides a mechanism for maintaining an area of skin tissue being confocal imaged under a stressed configuration by tension or compression, thereby minimizing the motion of this area with respect to a

> confocal imaging head. In the cervix the tissue being imaged is not skin as that term is commonly understood, but represents internal tissue of a patient. Internal tissues, for example which are surgically exposed, may be stabilized using the invention. [emphasis added]

Appellants submit that Furler, Saab, and Choi fail to cure the deficiencies of Zavislan, at least because neither Furler, Saab, nor Choi, alone or in proper combination, teaches or suggests how the skin examination device of Zavislan could be modified for scanning a plurality of substantially non-overlapping regions of "an internal biological sample, ... said sample not surgically exposed", as recited in independent claims 105 and 152. Furthermore, Appellants submit that the Examiner fails to establish a *prima facie* case of obviousness because the Examiner does not show how the cited art allegedly teaches or suggests the claim element, "an internal biological sample, ... said sample not surgically exposed", which is common to both of the pending independent claims, claims 105 and 152, in combination with the remaining claim elements. Appellants respectfully assert that none of the cited art teaches or suggests the combination of elements recited in either claim 105 or claim 152, and that these claims are patentable in light of the cited art.

As such, the Examiner's rejection fails to satisfy the requirements of 35 U.S.C. §103, because neither Zavislan, Furler, Saab nor Choi, alone or in proper combination, teaches or suggests every element of the invention as claimed.

Claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 constitute nonobvious subject matter and are patentable under 35 U.S.C. §103(a) over Zavislan in view of Furler, Saab or Choi, and further in view of Kittrell.

The Examiner has failed to find references that teach the limitations of claims 108, 111,

113, 118, 119, 121, 123, 148, 150, 162, and 168. The Examiner, in other words, has not met the basic requirements of 35 U.S.C. §103(a).

Dependent claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 depend, either directly or indirectly, from independent claims 105 or 152 respectively. As discussed above, neither Zavislan, Furler, Saab nor Choi, alone or in proper combination, teaches all the limitations of independent claims 105 and 152. Kittrell fails to cure the deficiencies of Zavislan, Furler, Saab and Choi, at least because Kittrell does not teach or suggest how the skin examination device of Zavislan could be modified for scanning a plurality of substantially non-overlapping regions of "an internal biological sample, ... said sample not surgically exposed", as recited in independent claims 105 and 152.

As such, at least for the reason discussed above, nothing in the cited art teaches or even suggests all the limitations of claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168. Thus, the Examiner's rejection fails to satisfy the requirements of 35 U.S.C. §103, because neither Zavislan, Furler, Saab, Choi, nor Kittrell, alone or in proper combination, teaches or suggests every element of the invention as claimed.

Claims 116, 117, 122, 124, 163, and 164 constitute nonobvious subject matter and are patentable under 35 U.S.C. §103(a) over Zavislan in view of Furler, Saab or Choi, and further in view of Kittrell and Raz.

The Examiner has failed to find references that teach the limitations of claims 116, 117, 122, 124, 163, and 164. The Examiner, in other words, has not met the basic requirements of 35 U.S.C. §103(a).

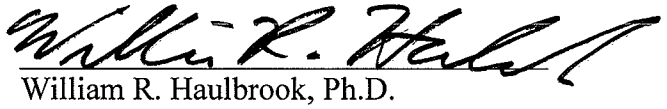
Dependent claims 116, 117, 122, 124, 163, and 164 depend, either directly or indirectly,

from independent claims 105 or 152 respectively. As discussed above, neither Zavislan, Furler, Saab or Choi, and Kittrell, alone or in proper combination, teach all the limitations of independent claims 105 and 152. Raz fails to cure the deficiencies of Zavislan, Furler, Saab, Choi, and Kittrell, at least because Raz does not teach or suggest how the skin examination device of Zavislan could be modified for scanning a plurality of substantially non-overlapping regions of "an internal biological sample, ... said sample not surgically exposed", as recited in independent claims 105 and 152.

As such, at least for the reason discussed above, nothing in the cited art teaches or suggests all the limitations of claims 116, 117, 122, 124, 163, and 164. Thus, the Examiner's rejection fails to satisfy the requirements of 35 U.S.C. §103, because neither Zavislan, Furler, Saab, Choi, Kittrell, nor Raz, alone or in proper combination, teaches or suggests every element of the invention as claimed.

In view of the arguments above, Appellants respectfully submit that claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 are patentable over the cited references. Appellants urge the Board of Patent Appeals and Interferences to reverse all of the Examiner's rejections as to all of the claims, and request allowance of claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 in due course.

Respectfully submitted,



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CLAIMS APPENDIX

1 – 104. (Canceled)

105. A method of sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample, the method comprising the steps of:

sequentially illuminating said plurality of substantially non-overlapping regions of said sample with electromagnetic radiation using illuminating optics, said sample not surgically exposed; and

collecting electromagnetic radiation emanating from said regions of said sample using collecting optics, wherein a disposable device for use with a single patient is positioned to protect said patient during said scanning.

106. The method of claim 105, wherein said illuminating step comprises focusing said illuminating radiation on said sample using a movable mirror.

107. The method of claim 105, wherein said collecting step comprises focusing said emanating radiation on a detector using a movable mirror.

108. The method of claim 105, further comprising the step of detecting electromagnetic radiation emanating from at least one of the regions of said sample and comparing said detected emanating radiation to at least one standard.

109. The method of claim 105, wherein said sample comprises biological tissue.

110. The method of claim 109, wherein said biological tissue comprises cervical tissue.

111. The method of claim 105, further comprising the step of diagnosing a disease state based upon a comparison of said emanating electromagnetic radiation to one or more standards indicative of various states of health.

112. (Canceled)

113. The method of claim 105, further comprising the step of selecting predetermined wavelengths of said emanating electromagnetic radiation for analysis.

114. (Canceled)

115. The method of claim 105, wherein said illuminating and emanating electromagnetic radiation pass through at least a portion of said disposable device.

116. The method of claim 108, further comprising detecting said emanating radiation with an array of detectors.

117. The method of claim 116, wherein said array of detectors comprises optical elements and processors.

118. The method of claim 107, wherein said movable mirror comprises a beam splitter to split said emanating radiation into a plurality of individual wavelengths.

119. The method of claim 118, wherein said beam splitter comprises a spectrometer.

120. (Canceled)

121. The method of claim 105, wherein a dimension of a field stop associated with said illuminating optics allows non-diffraction-limited illumination of a volume element of said sample.

122. The method of claim 105, further comprising the step of controlling an array of field stops in order to probe a volume element of said sample.

123. The method of claim 121, wherein said field stop is controlled by a movable mirror.

124. The method of claim 105, wherein said illuminating step comprises focusing said illuminating radiation on said sample using a plurality of movable mirrors.

125. The method of claim 106, wherein said mirror comprises a beam splitter.

126. The method of claim 105, wherein said disposable device is a single-use disposable sheath.

127 – 147. (Canceled)

148. The method of claim 105, further comprising the step of analyzing said collected radiation to determine one or more characteristics of said sample.

149. (Canceled)

150. The method of claim 108, wherein said detected radiation comprises at least one of scattered radiation and fluorescent radiation.

151. (Canceled)

152. An apparatus for sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample, the apparatus comprising:

illuminating optics for sequentially illuminating said plurality of substantially non-overlapping regions of said sample with electromagnetic radiation, said sample not surgically exposed;

collecting optics for collecting electromagnetic radiation emanating from said regions of said sample; and

a disposable device for use with a single patient, said disposable device configured to protect said patient during said scanning.

153. The apparatus of claim 152, wherein said illuminating optics comprises a movable mirror for focusing said illuminating radiation on said sample.

154. The apparatus of claim 152, further comprising at least one detector for detecting said emanating radiation.

155. The apparatus of claim 154, wherein said collecting optics comprises a movable mirror for focusing said emanating radiation on said at least one detector.

156. The apparatus of claim 155, wherein said movable mirror comprises a beam splitter.

157. (Canceled)

158. (Canceled)

159. The apparatus of claim 152, wherein said disposable device comprises a sheath interposed between a probe and said sample to prevent contact between said probe and said sample.

160. The apparatus of claim 159, wherein said sheath is configured to allow transmission of said illuminating and said emanating radiation.

161. (Canceled)

162. The apparatus of claim 152, wherein a dimension of at least one field stop associated with said illuminating optics allows non-diffraction-limited illumination of a volume element of said sample.

163. The apparatus of claim 152, further comprising an array of field stops for targeting said illuminating radiation to a plurality of volume elements of said sample.

164. The apparatus of claim 152, further comprising a plurality of mirrors for illuminating said regions of said sample.

165. The apparatus of claim 154, wherein said at least one detector comprises at least one optical element and at least one processor.

166. The apparatus of claim 154, wherein said at least one detector is adapted to detect at least one of scattered radiation and fluorescent radiation.

167. The apparatus of claim 152, wherein said disposable device is a single-use disposable sheath.

168. The apparatus of claim 162, further comprising a mirror for controlling said at least one field stop.

169. (Canceled)

170. The method of claim 105, wherein said disposable device is a disposable probe.

171. The apparatus of claim 152, wherein said disposable device is a disposable probe.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE